

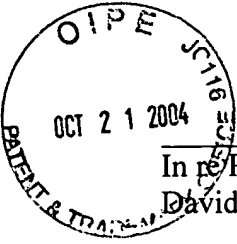
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1654

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Docket No.: 01946/100D864-US1  
(PATENT)



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
David Gschneider et al.

Application No.: 09/762,067

Confirmation No.: 7883

Filed: August 3, 2001

Art Unit: 1654

For: COMPOUNDS AND COMPOSITIONS FOR  
DELIVERING ACTIVE AGENTS

Examiner: Maury Audet

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

A copy of each document on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as

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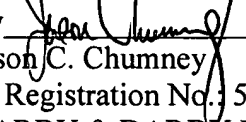
defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

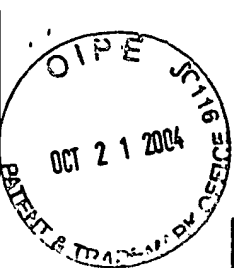
Our check in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: October 21, 2004

Respectfully submitted,

By   
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Attorneys/Agents For Applicant





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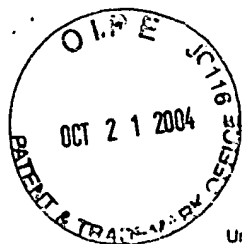
FEE TRANSMITTAL for FY 2005 <small>Effective 10/01/2004. Patent fees are subject to annual revision.</small>		Complete if Known	
		Application Number	09/762,067
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Filing Date	August 3, 2001
		First Named Inventor	David Gschneidner et al.
TOTAL AMOUNT OF PAYMENT (\$)		Examiner Name	Maury Audet
		Art Unit	1654
TOTAL AMOUNT OF PAYMENT (\$)		Attorney Docket No.	01946/100D864-US1

METHOD OF PAYMENT (check all that apply)		FEE CALCULATION (continued)																																											
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The Director is authorized to: (check all that apply) <input type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments <input checked="" type="checkbox"/> Charge any additional fee(s) or any underpayment of fee(s) <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.																																													
1. BASIC FILING FEE																																													
<table border="1"><thead><tr><th>Large Entity</th><th>Small Entity</th><th>Fee Code</th><th>Fee (\$)</th><th>Fee Description</th><th>Fee Paid</th></tr></thead><tbody><tr><td>1001</td><td>2001</td><td>790</td><td>395</td><td>Utility filing fee</td><td></td></tr><tr><td>1002</td><td>2002</td><td>350</td><td>175</td><td>Design filing fee</td><td></td></tr><tr><td>1003</td><td>2003</td><td>550</td><td>275</td><td>Plant filing fee</td><td></td></tr><tr><td>1004</td><td>2004</td><td>790</td><td>395</td><td>Reissue filing fee</td><td></td></tr><tr><td>1005</td><td>2005</td><td>160</td><td>80</td><td>Provisional filing fee</td><td></td></tr><tr><td colspan="5">SUBTOTAL (1)</td><td>0.00</td></tr></tbody></table>		Large Entity	Small Entity	Fee Code	Fee (\$)	Fee Description	Fee Paid	1001	2001	790	395	Utility filing fee		1002	2002	350	175	Design filing fee		1003	2003	550	275	Plant filing fee		1004	2004	790	395	Reissue filing fee		1005	2005	160	80	Provisional filing fee		SUBTOTAL (1)					0.00		
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SUBMITTED BY		(Complete if applicable)	
Name (Print/Type)	Jason C. Chumney	Registration No. (Attorney/Agent)	54,781
Signature		Telephone	(212) 527-7700
		Date	October 21, 2004

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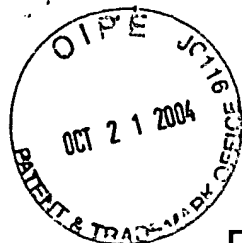
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			Application Number	09/762,067	
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			Art Unit	1654	
			Examiner Name	Maury Audet	
Sheet	1	of	3	Attorney Docket Number	01946/100D864-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Memorandum
		Number-Kind Code <sup>2</sup> (if known)			
	1	6,699,467	03/2/2004	Leone-Bay, et al.	
	2	6,693,208	02/17/2004	Gschneidner, et al.	
	3	6,693,073	02/17/2004	Milstein, et al.	
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	5	6,646,162	11/11/2003	Tang, et al.	
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	18	6,348,207	02/19/2002	Milstein, et al.	Certificate of Correction
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	27	US 2002-0001591	01/03/2002	Santiago, et al.	
	28	US 2002-0120009	08/29/2002	Leone-Bay, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>o</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	29	WO99/29705	06/17/1999	Glycomed Inc.		
	30	WO98/50341	11/12/1998	Emisphere Technologies, Inc.		
	31	WO98/25589	06/18/1998	Emisphere Technologies, Inc.		
	32	WO97/47270	12/18/1997	Arad, Dorit		
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			Art Unit	1654	
			Examiner Name	Maury Audet	
Sheet	2	of	3	Attorney Docket Number	01946/100D864-US1

36	WO03/057650	07/17/2003	Emisphere Technologies, Inc.		
37	WO03/057170	07/17/2003	Emisphere Technologies, Inc.		
38	WO03/045306	06/05/2003	Emisphere Technologies, Inc.		
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64	EP00/36145	09/23/1981	Inter, Research Corp.		
65	EP00/07979	05/18/2000	Dynamit Nobel AKtiengesellschaft		

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	66	LEONE-BAY, A. "Microsphere Formation in a Series of Derivatized Alpha-Amino Acids: Properties, Molecular Modeling, and Oral Delivery of Salmon Calcitonin"; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)			
	67	ANDREA LEONE-BAY "4-(4-Salicyloylaminophenyl)butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone" Medi 006, Presented at the American Chemical Society, (March 1996) New Orleans, LA			
	68	HO KOC-KAN; et al. " Solution Phase Preparation of Highly Pure Amide Mixtures Via In-Situ Chlorotrimethylsilane Protection and Activation" Synthetic Communication. vol. 27, no. 5: 883-895 (1997)			

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69	LEONE-BAY, A. "Synthesis And Evaluation Of Compounds That Facilitate The Gastrointestinal Absorption Of Heparin"; Journal of Medicinal Chemistry vol 41, 1163-1171 (1998)	
70	PICCIOLA G.: "Synthesis Of Quinazolinone And Benzoxazinone Acids And Study Of Their Anti-Inflammatory Properties" IT, Il Farmaco, Ed. Sc. vol 31, no. 9 pgs 655-664 - English Translation (1976)	Abs
71	PICCIOLA G.: "Synthesis Of Quinazolinone And Benzoxazinone Acids And Study Of Their Anti-Inflammatory Properties" Chem Abstract 86:5402t (1977)	
72	PALAGIANO, F., ET AL. "Synthesis, Stability And Anticonvulsant Activity Of Two New GABA Prodrugs" Pharmazie 52(4): 272-276 (1997)	
73	Chem Abstract 73548-12-6	
74	Chem Abstract 70204-54-5 (04/1991)	
75	Johansen, Marianne, et al. "The Kinetics of Decompn. Of Various N-Mannich Bases of Salicylamide" Int. J. Pharm. (1980), 7(2): 119-27 (1980)	
76	Rivera, Theresa M. et al. "Oral Delivery Of Heparin In Combination With Sodium n N-[8-2-Hydroxybenzoyl] Amino)Caprylate: Pharmacological Considerations" Pharmaceutical Research, Vol. 14(12) 1830-1834 (1997)	
77	Andrea Leone-Bay "4-(4-Salicyloylaminophenyl)Butyric Acid as a Novel Oral Delivery Agent For Recombinant Human Growth Hormone" Medi 006, Presented at the American Chemical Society, March 24-28, 1997 New Orleans, LA.	
78	Leone-Bay, A., et al. "The Evolution of an Oral Heparin Dosing Solution" Drugs of the Future Vol. 22(8) 885-891 (1997)	
79	Brayden, D. et al. "Heparin Absorption Across The Intestine: Effects of Sodium N-[8-2-Hydroxybenzoyl] Amino] Caprylate In rat in situ Intestinal Instillations Ind In Caco-2 Monolayers" Pharmaceutical Research Vol 14(2) 1772-1779 (1997)	
80	Leone-Bay, a. "Acylated Non-Alpha-Amino Acids As Novic Agents For The Oral Delivery Of Heparin Sodium, USP" Journal of Controlled Release 50: 41-49 (1998)	
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82	Leone-Bay, A. "N-Acylated Alpha-Amino Acids As Novel Oral Delivery Agents For Proteins"; Journal of Medicinal Chemistry Vol. 38, 4263-4269 (1995)	
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84	Gurrieri and Siracusa: "Thermal Condensation of Some Alpha-Aminoacids With Phthalic Acid" Thermochemica Acta, 7 (1973) 231-239.	
85	Brown, G. and Foubister, A.J. "Receptor Bindin Sites Of Hypoglycemic Sulfonyleureas and Related (Acylamino)Alkyl-[ ] Benzoic Acids Jmed Chem 27, 79-81 1984	
86	Chem Abstract 70(25) pp 311 (1969)	
87	Chemical Abstract, Vol. 99(23) Abst. No. 191473I (1983)	
88	Emisphere Technologies Poster Presentation, "Oral Delivery of Human Insulin In Diabetic Rats Using Novel Delivery Agents", Monica Carozza, et al. Nov. 16-19, 1998.	
89	Amino Yusuke et al. Chem Pharm Bull 36 pgs. 4426-4434 (1988).	

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